

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Ms. Wendy McCombie
Agent for Sterilex
Lewis and Harrison
122 C Street, N.W., Suite 740
Washington, DC 20001

OCT 17 2011

SUBJECT: Ultra-Kleen CW 502
EPA Registration Number: 63761-2
Application Date: June 17, 2011
Receipt Date: June 23, 2011

Dear Ms. McCombie:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), section 3 (C) 7 (A) as amended, is unacceptable due to the concerns listed below:

- 1) You have proposed to add directions for use to sanitize floors in dairy, food and beverage processing facilities. It is our understanding, from your e-mail dated 11/9/10 that you are basing this use on a claim for EPA Reg. No. 1677-223. You have proposed that your product be applied at a rate of 1.2-2.4 grams per square foot and that the product will become active when it contacts moisture on the floor.
- a) You may not add a claim to sanitize floors based on the data submitted for 1677-223. Your product contains active ingredients that differ from those found in 1677-223.
- b) Specific data was submitted in support of the floor sanitization claim for 1677-223. The data was based on the non food contact sanitization test using a very small amount of water along with an amount of product similar to what would be present for the floor use.
- c) Should you desire to add this use to your label, you must submit data for review based on the non food contact sanitization test using an amount of product and volume of water which would be expected at this site.
- d) In addition, revise this set of directions for use to indicate a minimum volume of water to be present on the floor which is in agreement with the testing provided.

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2) You have added directions for treatment of whirlpool bath, spa pool and Jacuzzi tub surfaces as well as pre-cleaning of whirlpool tubs. These uses are not on the label of the 63761-5 product (label dated 7/14/08) which you have referenced. Should you desire to add these directions to your label, site a similar product with directions for these uses.

3) Your label has not be revised to be in agreement with the last stamped label for this product dated 11/23/09. Make the following revisions as per the 11/23/09 Agency letter:

a) Revise the subsequent dose for the drain claim to indicate that the treatment is to be made every seven days.

b) Revise the Precautionary Statements

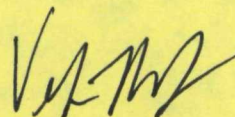
c) Revise the Environmental Hazards

4) There are several instances on your label (e.g. page 4 ultrasonic bath directions and page 5 veterinary facilities) that indicate the pre-cleaning directions are "below." The pre-cleaning directions on the master label precede both of these sections. If you intend to keep the term "below" in those sections, revise the order of your label to insure that the pre-cleaning directions follow each of these sections.

General Comments

This is a cursory label review. A complete review will be completed when the revisions above are submitted along with supporting efficacy data. Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415 or Velma Noble at (703) 308-6233.

Sincerely,



Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510P)

7510P:T.Lantz:10/17/11:63761-2c unaccepted label amend

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